EXHIBIT 515

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

BOBBY R. MILLIGAN, et al., Plaintiffs, -vs- ACTAVIS GROUP HF, et al., Defendants.	MDL Case No. 2:09-cv-121 VIDEOTAPED DEPOSITION OF: RUSSELL F. SOMMA, PH.D.

TRANSCRIPT of testimony as taken by and before MARK SCHAFFER, a Certified Shorthand Reporter and Notary Public of the States of New Jersey and New York, at the Marriott Hotel, Newark Liberty International Airport, Newark, New Jersey, on Thursday, July 1, 2010, commencing at 8:31 in the forenoon.

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ALSO PRESENT: ADAM DICOLA, Videographer

I N D E X

E X H I B I T S

THE VIDEOGRAPHER: Good morning. We are now on the record at 8:31 a.m. The date today is July 1st, 2010. This is the videotaped deposition of Dr. Russell F. Somma in the matter of In Re: Digitek Product Liability Litigation in the United States District Court for the Southern District of West Virginia, Charleston Division, MDL Case Number 2:02-CV-121.

I am the videographer; my name is Adam Dicola of Rennillo Court Reporting. The court reporter is Mark Schaffer, also with Rennillo Court Reporting.

Will counsel please state their appearances for the record?

MR. MILLER: Pete Miller with the Miller firm for plaintiffs.

MS. CARTER: Meghan Carter with Motley, Rice for the plaintiffs.

MS. DOWNIE: Ericka Downie, Shook, Hardy & Bacon, for the Mylan defendants.

MR. MORIARTY: Mathew Moriarty, Tucker Ellis & West, for the Actavis defendants.

R U S S E L L F. S O M M A,

Five Shady Lane, Sparta, New Jersey 07871,

having been duly sworn according to law by the Officer, testified as follows:

DIRECT EXAMINATION BY MR. MORIARTY:

MR. MILLER: Matt, before you get started, I would like to point out something. I spoke to the doctor yesterday evening and he saw what he believes to be something in error in his report that he'd like to fix. We can address it now or wait until you discuss the report.

MR. MORIARTY: Let's wait.

MR. MILLER: Okay.

Q. Let me know.

A. Okay.

Q. Good morning.

A. Thanks. Thanks. Good morning to you.

Q. How many times have you had your deposition taken before?

A. Never.

Q. Other than the Digitek litigation, how many times have you been consulted as an expert witness?

A. Never.

Q. I'm sure Mr. Miller or Ms. Carter has given you some information about what's going to happen today. Okay? Is that right?

A. Yes, sir.
Q. We are going to spend all day. I'm going to ask you a lot of questions. And your function is to just to answer my questions; okay?
A. Yes, sir.
Q. If you do not understand my question, please tell me you don't understand my question. Okay?
A. Okay.
Q. If you answer the question, I'm going to understand -- I'm going to assume that you at least understood it. Is that okay?
A. Okay. I will ask.
Q. Okay.
A. No stretching.
Q. And if you need to look at documents, please look at documents. I don't want you to guess at the answers to any of my questions. Okay?
A. Okay.
Q. And also sometimes witnesses want to talk and talk and talk and lecture me about good manufacturing practices and various other topics. I'm going to try to keep my questions quite specific. Okay?
A. Okay.
Q. So if you can answer my questions, I would appreciate that. Okay?

A. Okay. So that would mean that there would have to be some exchange between us, so I understand exactly --

Q. Yes. I'll give you a chance to explain if I need something explained, but I would like direct answers to my questions. Okay?

A. Uh-huh, yes, sir.

Q. This is Exhibit 51.

Is that your resume?

A. Yes, it is.

Q. All right. And while I'm at it, this is Exhibit 52.

A. That's my report, yes.

Q. Is this your report --

A. Yes.

Q. -- in this litigation?

A. Uh-huh, yes, it is.

Q. And at the back of your report in Appendix A, it says, "Materials reviewed." Right?

A. Yes, sir.

Q. And I assume that at least before writing the report, these are the things that you looked at. Is that correct?

A. That's correct.

Q. And when were you first consulted in this

litigation?

A. I was contacted in March.

Q. Of 2010?

A. Of 2010.

Q. So I assume as you received material over time, you have had an opportunity to read it?

A. As I got the material I did read it, yes.

Q. And you had plenty of time to draft this report. Is that correct?

A. Yes, sir.

Q. I assume that there were drafts to this report?

A. Yes, sir.

Q. Did you save drafts?

A. Yes, I did.

Q. And then I assume that you had some time to talk with members of the plaintiffs' side of this case about those drafts leading to the final version. Is that right?

A. That's correct, yes.

Q. Okay. And that's fine. You have never done this before. You didn't know anything about it. They gave you some guidance on things that may need to be in there or not; right?

A. Well, Matt, actually what I did --

MR. MILLER: Object to form.
Q. One rule is you have to let me finish my questions --
A. Sorry, sorry.
Q. Because, Mark, the court reporter, can't take us both down at the same time.
A. I got you.
Q. Okay?
A. I got you.
Q. Okay.
A. Can I ask my question now?
Q. Well, actually you don't get to ask questions.
A. Oh, okay.
Q. I do.
MR. MILLER: But there is a question pending. You had asked him --
MR. MORIARTY: I asked if he had time to talk with the plaintiffs' side about the report.
A. Right, and I agreed.
Q. Okay. And there -- there is a mistake in it somewhere and we'll get to that later.
A. Right.
Q. Okay?
A. Uh-huh.

Q. Did the plaintiffs' side of the case let you know, the lawyers let you know, that the purpose of this report is to put people like me on notice of what your opinions were in the litigation?

A. Yes, sir.

Q. And you tried to put all your opinions in there?

A. That I came away with after I read what I had, my opinions based on my experience, yes.

Q. Have you read additional material since writing this report?

A. Yes, sir, I have.

Q. We'll get to that later.

Okay. So you were first contacted in March. And who contacted you?

A. An organization by the name of Spyglass. They were looking for somebody to provide expert input, with experience in tableting.

Q. I assume you mean --

(A discussion is held off the record.)

A. With experience in tableting. Compression. Sorry.

Q. I assume you mean Mark Kenny?

A. That's correct, right.

Q. And did he make direct contact with you?

A. Yes, he did.
Q. Have you ever met him before?
A. Not before then, no.
Q. How did he know about you?
A. A network of consultants; knows people, and they worked with another fellow that I worked with at Novartis.
Q. What's his name?
A. Alp Yaman.
Q. I'm sorry?
A. Alp Yaman.
Q. Now, you have a company called Somma Tech Consulting; do you not?
A. That's correct.
Q. Is it a corporation, a partnership?
A. It's an LLC, and my partners are the parent company, IPS.
Q. IPS?
A. Integrated Project Services.
Q. How many employees does Somma Tech Consulting have?
A. We have two.
Q. Who are they?
A. Me and a ten -- excuse me -- I should correct that. 1099 doesn't constitute an employee, so we have

me and a woman that does our transdermal work at the present time.

Q. What do you mean does your "transdermal work at the present time"?

A. She consults in an area of transdermal delivery systems for another firm that we work for.

Q. Okay. What's her name?

A. Amanda Gotto.

Q. Say that again?

A. Amanda Gotto.

Q. Is Amanda Gotto consulting in any other litigation?

A. No.

Q. Has Amanda Gotto had any input into your analysis or report in the Digitek litigation?

A. No.

Q. And then who is IPS?

A. IPS is a company that Somma Tech is a part of. It's an engineering project management -- project management firm.

Q. In fields other than pharmaceutical?

A. They are predominantly in pharmaceutical, but they have been known to do work in other areas on the soft side; not heavy industry.

Q. I assume that they are a consulting group?

A. That's correct.
Q. Did anyone from IPS have any input into your analysis for the drafting of your report in the Digitek litigation?
A. No, they have not.
Q. I assume that you are charging the plaintiffs' lawyers for the time that you have spent reviewing material and writing your report?
A. Yes, I have. Yes.
Q. Is that right?
A. Yes.
Q. How much are you charging for that?
A. $350 an hour, Matt.
Q. I assume you are charging me for the time we spend all day today with me questioning you about your report. Is that right?
A. If you would like, yes.
Q. Well, I prefer not, but I assume you are going to. So why don't you tell me how much I am going to be charged.
A. $350 an hour.
Q. Thank you.
Do you have any idea how many bills you have already sent the plaintiffs' lawyers for your review to date?

A. Three.
Q. What's the total of those bills?
A. $40,000.
Q. How much do you have in unbilled time up to today?
A. I would say about 30,000.
Q. So, just so I'm clear, you think that the total amount of time that you have put into this review and writing to date is about $70,000?
A. No, no. In other words, as I can tell -- I have a time management system that we put in our time for. Based on that time, there is about $40,000 in billing. Okay?
Q. Okay.
A. And those invoices, we have been paid the first invoice, which was the initial retainer; but since then we have not provided -- we haven't provided the invoices on a more timely basis.
Q. So you believe that the total amount of time, the value of the time you have put into this is about $40,000?
A. That's correct, Matt, yes. Sorry.
Was that too long of an answer, Matt, just so we know going forward?
Q. No. "Yes" is good. I really like that.

You have a Ph.D. in pharmaceutical science from Rutgers; do you not?

A. Yes.

Q. Now in your day-to-day wanderings about the world including your consulting work, are you called "Mister" or "Doctor"?

A. Well, I never really paid much attention to it, but most of my clients refer to me as "Doctor," you know.

Q. Okay. Dr. Somma, have you ever --

A. That doesn't include you, by the way.

Q. Okay. So I can call you Mister?

A. No, "Russ" is good. But go ahead.

Q. In your industry experience, and I understand that that was primarily at Novartis. Is that correct?

A. That's right, yes.

Q. Did you ever work on a digoxin product?

A. I worked on a cardiac glycoside, yes, sir. I worked on Serpasil. Serpasil is in the same general class. Is it digoxin? No, sir.

Q. Is it digitalis?

A. No, sir, it's reserpine.

Q. Is it derived from the "something-lanata" plants that --

A. It's a natural alkaloid. I can't tell you if

it's from the same plant, no, sir.

Q. And is Novartis' cardiac glycoside product an IV or a solid oral base?

A. Solid oral dosage form.

Q. And what was your involvement with that?

A. Production support and troubleshooting.

Q. Okay.

A. Just for clarity, it was Ciba at the time.

Q. How did you -- How long did your duties involve that product?

A. These things came up periodically, so your responsibility was the product line. So reserpine or Serpasil in this case was the hot topic for six, eight months, and then it would go -- you would go onto the next product or problem. Is that clear?

Q. Yes. When you were working on -- was it a product that was in full commercial production?

A. Yes, sir, it was.

Q. Did you have any role at all in adverse event reporting analysis for that product?

A. No, sir.

Q. Were you at least aware that the drug is known to have a narrow toxic therapeutic window?

A. When I worked on the drug, the term "narrow therapeutic window" wasn't commonly used. It was just

a low dose drug for us, and to me that was the issue in that case.

Q. When you say "low dose drug," are you talking about the actual amount of the active pharmaceutical ingredient in the tablet?

A. That's correct.

(A discussion is held off the record.)

A. The amount of active ingredient in the dosage form. In this case, less than a milligram.

Q. And do you know what the dose strengths were of reserpine when it was -- when you were dealing with it at Ciba?

A. I would have to guess, but point-one as I recall is one of them.

Q. Do you know if they made a 0.5 milligram dose?

A. That I can reasonably say with assurance, no.

Q. When were you involved with reserpine?

A. Reserpine was back in 1976.

Q. Okay. This is long before the FDA's digoxin regulations?

A. It was around the same time, because I remember a lot of digoxin noise when I was in pharmacy school about, you know, different products; but primarily that wasn't on my radar screen at all.

Q. Did they ever put in an NDA for reserpine?
A. Yes, it was; it was an NDA.
Q. When?
A. That I don't know, sir.
Q. Did you ever have anything to do with the quality control chemistry testing of reserpine?
A. Chemistry testing, no, sir.
Q. Do you know what kind of tablet presses they used?
A. Yes, sir.
Q. What?
A. Manesty Mark II.
(A discussion is held off the record.)
Q. The difficulty that Mark, the court reporter, is having is that you are looking at me and it just makes it a little harder for him. And that's unfortunately the way this room is set up and kind of the way it has to be. Okay?
A. All right.
Q. Did Manesty Mark II tablet presses have weight control equipment on them?
A. They did, sir, yes.
Q. When they had weight control on them, did they weigh all produced tablets or just random samples?

A. Let me -- let me -- let me -- If I may, Matt. Matt, Manesty Mk II's have weight control on them. If your question is -- if your question is: Did we use those to make reserpine? Is that -- or am I jumping ahead here?

Q. Well, I asked you what kind of tablet presses --

A. Manesty Mark II's.

Q. -- presses Ciba used to make reserpine?

A. That's right.

Q. Did the Manesty Mark II's that were used to make reserpine have weight controls?

A. The ones that we owned that made reserpine, no, sir. Okay? Sorry. I was thinking of it in a global sense.

The answer is: They do have them. We didn't have it on that machine.

MR. MILLER: No, that's fine. You are doing fine.

Q. So the -- So whatever in-process weighing, measuring and hardness testing was done, was done either by a QA employee or -- and/or a press operator. Is that right?

A. That's correct.

Q. Do you have any memory of how often the QA

person came in to check thickness, hardness and weight?

A. The QA person, I don't recall, sir, no.

Q. Do you know how often the tablet press operator was expected to check samples of thickness, hardness or weight?

A. Every half hour is our custom.

Q. How much of your work in your industry experience was solid oral dose?

A. I would say 98 percent of it, sir.

Q. And you worked essentially from the conclusion of your bachelor's in pharmacy until you left private industry at Novartis or its predecessor companies. Is that right?

A. That's correct.

Q. Almost 30 years?

A. Almost, sir.

Q. Why did you leave Novartis in June of 2004?

A. I retired -- not retired. Excuse me. I resigned. Sorry about that. To be clear, I resigned. I resigned.

The opportunity came up with people I've worked with at various associations and different professional groups that it seemed to me that owning my own company was going to be an opportunity to

explore and expand and share my background. I had gotten quite a lot of airplay from work we had done. Bottom line was: I capitalized on things I had in place, left, and started my own company. That is why IPS is my partner.

Q. And what are you, about 58 years old?

A. Fifty-nine.

Q. Now, in your industry experience at Novartis and its predecessors, did you have any experience in dealing with the FDA in inspections?

A. Yes, sir.

Q. And I assume that happened over the years, FDA would come in and conduct inspections?

A. Yes, sir, primarily pre-approval inspections for drugs.

Q. Did you ever have any experience in remediating 483s or warning letters that were given to your employer?

A. 483s, sir; warning letters, no.

Q. What about establishment inspection reports?

A. I was aware of their existence.

Q. Did you ever have any experience with product recalls when you were in your industry experience?

A. Yes, sir.

Q. What was the product that was recalled?

How many recalls were you involved with? Let's put it that way.

A. I would say two, sir.

Q. Were they solid, oral dose?

A. Yes, sir.

Q. What were the reasons for the -- and can you tell me what the products were? I assume it's public knowledge?

A. Well, I think -- well, one of them was a -- a field action for a carbamazepine.

Q. Okay.

A. Carbamazepine I believe is Tegretol.

Q. Why was carbamazepine recalled?

A. It was I believe -- and, again, the recall was the key; I don't recall if it was a voluntary recall. The key was that we had found anomalies in the tableting operation.

Q. Okay.

A. And these were in hardness dose specifications.

Q. Was the recall a precautionary recall?

A. Yes, sir.

Q. Was it to the consumer level?

A. That I don't remember, sir.

Q. To the best of your memory, did you ever find

any car --

A. Carbamazepine.

Q. -- carbamazepine tablets actually in the field that failed your specifications?

A. From the best of my memory, I don't recall bringing them back. Because we primarily would depend upon our retained samples to assess what's in the field.

Q. Okay.

A. Understanding, of course, that what's in the field you have no control where it's been, so we went by retains.

Q. Okay.

A. But when they came back, we tested them.

Q. All right.

A. Right.

Q. What do you mean, "when they came back"?

A. When the samples came back from -- a complaint sample would come back, we would test those.

Q. Yes. Okay. And the ones that were tested, were they out of spec?

A. That I don't recall, sir, right now specifically, to be honest.

Q. Well, sometimes in the pharmaceutical industry you do a recall even though the product in

the field may not actually be out of spec; correct?
A. That's right. Out of precaution, correct.
Q. Okay. So what was the second recall that you had anything to do with?
(A discussion is held off the record.)
Q. And, again, I told you in the beginning, that if you don't know the answer to my question, I don't want you to guess.
A. No. I think in that particular case it would take -- it would be a stretch for me to answer the second recall question.
Q. Was it a solid oral dose?
A. Yes, it was.
Q. Do you remember what the problem was? Or why the --
A. I believe -- I believe it was dissolution, as I recall. That was -- and I think that's about as best I can do. I think -- We used to monitor levels, S1, S2 levels.
Q. Okay. When you were at Novartis and its predecessors, did you ever have -- did you ever reject batches that didn't meet the specifications?
A. I was not in that position, no, sir.
Q. Do you know whether it happened?
A. Rejection of batches? Yes, sir.

Q. Okay. And certainly out-of-spec investigations occurred from time to time?

A. Absolutely.

Q. Is that right?

A. Absolutely.

Q. Now, what -- Were you in the Manufacturing Division, the Quality Department --

A. Research and Development.

Q. Research and Development. Did you ever get involved in products that were in full-scale commercial development?

A. Yes, sir.

Q. I'm sorry. Full-scale commercial production?

A. Yes, sir.

Q. And did you spend most of your career in Research and Development?

A. I was all -- my entire career was in research and development, which included product production at some point.

Q. And I assume that's one of the reasons why one of your particular interests in pharmaceuticals is what's known as scale-up. Is that correct, sir?

A. That's correct, sir.

Q. And technology transfer?

A. That's correct.

Q. And in my plain English, the -- the science of going from research and development small batch sizes to full commercial production scale pharmaceutical manufacturing; correct?

A. That's correct. And even in simpler terms, it's simply moving it from Place A to Place B.

Q. Place A little and Place B big?

A. Or Place A little to Place B little, to minimize problems. Okay?

Q. At Page 4 of your resume, you have Publications and Presentations.

A. Uh-huh.

Q. Do any of them involve digoxin?

A. No, sir.

Q. Do any of them involve troubleshooting of oversized tablets?

A. To the best of my knowledge no, sir. I'm checking as we're going, just to make sure I'm giving you the right --

MR. MILLER: That's fine. If you need to check, go ahead and check.

A. I doubt specifically oversize.

Q. You wrote them. I didn't.

A. Yeah.

Q. Do any of them have anything to do with the

appropriate ways to get to a root cause analysis?

A. While none of them speaks to that topic by inference, I think that these types of things are tools that would be used in a root cause analysis, but they are not titled such.

Q. Okay.

A. Okay?

Q. When was the first time you met in person with somebody from the plaintiffs' lawyers group in this case?

A. I think -- I'm guessing -- No, I'm not going to guess.

Well, not to waste time, I'm thinking mid -- late May, mid May, something like that.

Q. Who has been your primary contact?

A. Meghan Johnson.

Q. I assume you spent some time with plaintiffs' lawyers either this morning or yesterday preparing for your deposition today?

A. Yes, sir.

Q. Who did you meet with with?

A. I met with Meghan and Pete Miller.

Q. And did they tell you anything about the deposition testimony of a Mr. Farley that took place in Savannah, Georgia on Monday?

A. No, sir.
Q. Did they tell you anything at all about the deposition testimony of Mark Kenny that took place in this room on Tuesday?
A. No, sir.
Q. Did they tell you anything about the deposition testimony of a Dr. Frank that took place in Philadelphia yesterday?
A. No, sir.
Q. Have you read the reports of any other experts in this case?
A. No, sir.
Q. No Dr. Semigran, no Dr. Nelson?
A. No, sir.
Q. Not Farley, Frank?
A. No.
Q. Etc., etc.?
A. No. If I had a guide, I probably wouldn't have made the mistake I told you about. Do you know what I mean?
Q. I --
A. Okay.
Q. Other than Pete Miller and Meghan, who have you talked with about this litigation?
(A discussion is held off the record.)

A. That would be the guy at Spyglass, Mark Kenny.

Q. Did you talk to him about substance or just logistics?

A. I think part of it was -- when you say "logistics," who is going to do what?

Q. Who is going to do what, here's who to call, things like that?

A. That was partly, partly --

Q. Did you talk about the substance of the litigation, what the claims were?

A. When we first met with them. Because like I said, we had been contacted and they explained to me what this was about. So I think in that particular case, there was a substantive amount of discussion, yes, sir.

Q. Did you meet with Mark Kenny in person?

A. Yes, sir.

Q. Where did you meet?

A. In Chester, New Jersey.

Q. Was there anybody else present?

A. As I recall, Sal Romano was present as well.

Q. All right. Did you keep any notes from that meeting?

A. Those I did not sir, no.

Q. And I see you have a spiral bound notebook in front of you. Is that correct?

A. That's right.

Q. Is that notes about substance, or just your ongoing logistical work in the matter?

A. Because -- actually, it's everything that I've done. If -- in other words, if I've read -- if I've read a lot of material, I'll make notes in here rather than try to make a paper copy. Or if I have a meeting, I'll put the notes in here.

I did not start this, because when I talked to the guys at Spyglass -- excuse me -- Mark Kenny, I hadn't been selected to do the job.

Q. All right. Did you bring a photocopy of your notebook today?

A. No, sir, I did not.

MR. MORIARTY: At some point today we will have to mark the notebook and make sure we get copies of the notes.

MR. MILLER: Okay.

Q. So other than Pete and Meghan and Sal and Mark Kenny, have you talked to anybody else about this litigation?

A. Well, we visited Actavis and I talked to Michael Anderton, right? So I guess that counts too.

Q. Right. And whoever else was along that day?
A. Was there -- I forget. There was a -- well, there was Michael and the guys from Actavis. I didn't talk to them obviously, but --
Q. What I really want to know is: Did you talk to anybody else about the substance of the litigation?
A. No, sir.
Q. Do you have any military service?
A. No, sir.
Q. Have you ever been a professor at any school?
A. My teaching assignment was limited to my residency for my doctorate.
Q. Do you consider yourself to be an expert in pharmacokinetics?
A. No, sir.
Q. Pharmacology?
A. No, sir.
Q. Pharmacovigilance?
A. No, sir.
Q. Do you consider yourself to be an expert in the regulatory aspect of the pharmaceutical industry?
A. I'm familiar with the regulatory aspect in the amount that it requires me when I do my job, because it's a regulated industry. Am I an expert? No, sir.

Q. Are you an expert in quality assurance?
A. No, sir. And, again, where it overlaps into what I do:
Q. Okay. And I asked you I think a little bit before: You don't consider yourself to be an expert in quality control chemistry?
A. No, sir.
Q. Have you ever looked at the Digitek detailed patient labeling?
A. Yes, sir.
Q. Have you ever looked at the United States Pharmacopeia monograph regarding digoxin?
A. Yes, sir.
Q. Did you ever look at the USP monograph about digoxin as part of your work in industry?
A. No.
Q. Have you ever looked at at the USP monograph on digoxin before your litigation consulting in this case?
A. There was no reason to. No, I did not.
Q. Now, let's get back to your report.
Exhibit 52, I believe it is, Appendix A. Would it be safe for me to say that a lot of what you relied on for your analysis in this case was FDA Form 483s and warning letters?

A. I wouldn't say predominantly, no. I think I looked for more content in technical information, batch records, investigations, internal documents. That's my -- my -- what I -- customarily how I do that.

Q. All right. In Appendix A, the only batch record I see listed is seven -- it should be 70924A. You actually have a typo here.

A. Yes.

Q. It's the second item from the end.

A. Yeah.

Q. Is that the only batch record you reviewed?

A. No, sir.

Q. What other batch records did you review?

And while you are looking for those, are these batch records that you received subsequent to drafting your report?

A. No.

Q. So you reviewed other batch records, but did not put them in Appendix A?

A. That's correct. I think because -- Well, let me find it first so I understand what you are talking about.

71005A.

Q. 71005A?

A. 5A.
Q. Okay. What else?
I'm sorry. I have a question about that.
Is that the complete batch record?
A. That I couldn't say.
Q. Does it have the mixing information?
A. It has the procedures necessary to make the blend and the tablets. The M -- M --
Q. Well, wait a minute. Just answer my question.
A. Yeah.
Q. Does it having mixing information with the weighing and measuring of the excipients and the active pharmaceutical ingredient?
A. Yes, sir.
Q. It has the blending information?
A. Yes, sir.
Q. Does it have the chromatography for the blend uniformity samples?
A. It has the results. It doesn't have the raw data.
Q. All right. Does it have the in-process tableting data, such as the QA and the operator checks?
A. Yes, it does, sir.

Q. Does it have the results of the quality control testing, such as assay and content uniformity?
A. Yes, it does.
Q. Does it have the packaging information?
A. It looks like it does, sir, yes.
Q. Okay. What other batch records did you review besides 70924A and 71005A?
A. Those are the only two I looked at before I wrote the report.
Q. Do you know how many batches were included in the recall?
A. I don't recall, sir.
Q. Do you know that we have produced at least 152 batch records to the plaintiffs' lawyers in this case?
A. I didn't know that number. I would imagine the product has a lot of batch records, yeah.
Q. Did you ask to look at any more batch records?
A. Yes, I did.
Q. And what happened with that?
A. I -- subsequent to my request, they put more on the site for me to look at, yes.
Q. They put more on the site?
A. We have a -- there is a database that some of

this information be placed on for me to access. And I was able to go in there and take a look.

Q. Did you?

A. Yes, sir.

Q. Okay. My question was: What other batch records did you look at besides 70924 and 71005.

So what batch records did you look at on this site?

A. I don't remember the numbers, to be honest with you, sir.

Q. How many batch records did you look at?

A. It must have been at least three.

Q. Were 152 batch records available on the site?

A. That I don't know, sir.

Q. What's the web address for the site?

A. It's Crivella.com, the W -- the web address.

Q. That's good. Is this a website for which you needed a password?

A. Yes, it is.

Q. Did you make note anywhere in your notebook of what other batch records you reviewed on line?

A. No, sir. You will find these two that we just talked about.

Q. All right. Other than what's on Exhibit -- I'm sorry -- Appendix A, what else have you reviewed?

A. I've looked at everything that's on these drives.

Q. You are pointing to a little white box that presumably has a thumb drive in it?

A. Several thumb drives, sir.

Q. Are they -- is there different material on those two thumb drives?

A. Actually, yeah, there's three.

MR. MILLER: Three.

A. And there is documents that were pulled from the site and -- on two of them, which are these two.

And I'm not clairvoyant. I have them written on the back. I see you looking at me.

And the third one is e-mails that you have asked to see.

Q. All right. Now, are those thumb drives duplicates that I can take, or do they have to be duplicated?

A. No, sir, these are -- you requested these and these are for you.

Q. Okay. Thanks for the little white box, too. I appreciate it.

A. Well, I realize you wanted yes or no, but the answer is: You'll lose them, believe me. So I put them in a box. Sorry.

Q. Could you give them to Mark, please?
A. Sure. Mark.
Q. That Mark.
A. There you go.
MR. MORIARTY: Mark, mark it.
(D-51A, White Box Containing Three Thumb Drives marked for identification.)
Q. Dr. Somma, is 51 -- Exhibit 51A the little white box with the three thumb drives on it that we just discussed?
A. Yes, sir.
Q. Okay. Can I have that?
A. Sure thing.
Q. And just so I make sure I understand what is on it, on those thumb drives, is that material in addition to Appendix A?
A. Yes, sir. And the drafts.
Q. Drafts of your report?
A. And -- yes.
Q. You are very organized. I appreciate that.
A. Well, you made a pretty good list, Matt, so...
Q. I see at the end of Exhibit A that you reviewed the depositions of Richard Dowling, Phyllis Lambridis, Dan Bitler and Scott Talbot. Is that

correct?

A. Yes, sir.

Q. Did you read the whole deposition? They're kind of long?

A. They're really long. I went through them and I got a -- I started skimming stuff, looking for pieces.

Q. Did you make notes anywhere of things that any of those four witnesses said --

A. Yes.

Q. -- that you disagreed with?

A. Disagreed?

Q. Disagreed.

A. I would have to actually look at all my notes. I made notes about things they said. Whether I disagreed or agreed, I can't say yes or no.

Q. Okay. We'll look at your notes later. If I have time for that, I'll go back to it.

A. Okay.

Q. Did you ever look at the ANDA?

A. Yes, sir, I did.

Q. Is that on Appendix A or --

A. That's on the jump drives. Excuse me. Thumb drives.

Q. Now, when you are -- what kind of things is

SommaTech asked to do in your consulting practice?

A. Like I -- just to make the connection, when I left Novartis, my reputation was for scale-up and fixing production problems.

Q. Okay.

A. So as soon as we put the shingle out, we started fixing people's problems. My expertise in several areas, that was people -- the network knew I was out about; I got contacted.

Q. All right. Have you ever been consulted as part of SommaTech for an over-thick or overweight tableting problem?

A. Yes, sir.

Q. Go back to your industry experience. And I'm sorry for jumping around.

A. That's okay.

Q. Did you ever have overweight or over-thick tableting problems at Novartis?

A. Not that I recall.

Q. Are you -- is the identity of your consulting client with the double -- or the overweight or over-thick tableting problem, are you able to discuss that consulting?

A. To be honest, just so -- the way consulting works in our business, because we sign CEAs.

Q. Okay.
A. Yeah, so I --
Q. All you have to do is say "No, I can't discuss it."
A. Okay. I want to try to make sure you know: We are not a mom and pop operation, so --
Q. I understand. So what was the specific tableting problem that this consulting client had?
A. That tablets which were oversized essentially got into distribution.
Q. All right. Did you ever figure out how many --
A. No.
Q. -- oversized tablets had gotten into distribution?
A. No, sir.
Q. Is that consulting engagement closed?
A. Absolutely, sir. In fact, in that particular case, for clarity, we were consulting on a different issue, on a different product, and this came about and we were asked. Okay?
Q. Okay. What did you look at once they said, "We have this oversized tableting problem;" what did you do, what documents did you look at, who did you talk with to try to figure out what the problem was?

A. We did a -- again, to be clear, our involvement in this was not heavy.

They asked us to look. We looked at the batch records in this particular case, which are similar to what we looked at in this situation.

Q. Okay.

A. And we did not see any anomalous behavior.

Q. How many -- go ahead.

A. Excuse me. I'm fine.

Q. How many batch records did you look at as part of that consulting engagement?

A. In that particular case, I looked at the batch in question or the batch they said they had the problem with, and a previous batch, you know, what was the batch before that and what was the batch after that. Only because that's my -- my approach to things.

Q. Okay. And, you know, I don't remember off the top of my head what Batch 71005A was. Do you remember when it was --

A. I'd have to look.

Q. -- compressed? I mean, maybe you remember off the top of your head that it was a preceding --

(A discussion is held off the record.)

Q. -- or following 70924?

A. I could probably give you a better sense of that as soon as I look at the date. My --

Q. If you just tell me the date, that's fine?

A. The date on this is December 17th, '07. This is during the compression sheet.

Q. Okay. So it was close in time to 70924?

A. Yeah, but I wouldn't say that it was like right next to each other.

Q. That's fine. So for that consulting client, they had produced some extra-thick tablets. Is that right?

A. That's correct.

Q. And some of them, were they verified to have made it out into the marketplace?

A. Yes, sir.

Q. Was there a recall involved?

A. Yes, sir. Again, as that started to -- just so you got a full disclosure, as that started to gather and evolve, they were aware of it, they were going to take action, and voluntary subsequent to that the thing really took on a life of its own. Okay?

Q. Okay.

A. We were not involved in that aspect. Just want to give you a sense of it, so you don't assume I was sitting there at the helm. Okay?

Sorry to babble on, but I didn't want you to waste your time going down that street, you know.

Q. But when you looked --

A. Right.

Q. -- at the batch records --

A. Right.

Q. -- you didn't see a problem?

A. No, sir.

Q. You didn't see anything like a validated process that was out of control?

A. You see, your first step is: You look at the batch record. I didn't see anything. Customarily the next thing you would do is look at the validation. I didn't do that. Okay? So I don't make that assumption, I don't make that leap until I look at it. Okay?

Q. All right. I'd like you to look at Exhibit 52?

A. Yes, sir.

Q. Third full paragraph.

A. Yes, sir.

Q. Oh, I'm sorry. The very end of the first full paragraph. You were an "invited investigator trainer and liaison for the FDA on various projects and initiatives"?

A. Yes, sir.
Q. What projects and initiatives were those?
A. They had a project to train their field investigators who were not that knowledgeable in industry -- common industry practices.
So at the time, it was customary for the field officers or people in the Compliance branch to identify people in industry to come in and teach.
Q. Okay. And what did you teach?
A. On matrix tablets.
Q. What are matrix tablets?
A. Matrix tablets is a term that's used in the industry to define a timed-release tablet, a sustained release.
Q. Third full paragraph. You refer to yourself as a "recognized industry subject matter expert."
What do you mean, "recognized"?
A. That people come to me and employ my services in technology transfer.
Q. Next full paragraph, you're talking about some publications. Are you sure that those publications are peer reviewed?
A. Yes, sir.
Q. Okay.
A. I have to change glasses. Excuse me.

Q. Go to Page 2, please. In the Introduction sentence -- I'm sorry. In the Introduction section, the first sentence and the last sentence refer to "our review."

A. Right.

Q. Who is "our"?

A. I have to note that when I write things in general, it's my habit to write in the "we, our." Simply because as a firm, I write that. It should be -- I hope I'm making sense. It's SommaTech's opinion, the answer is that's how I write things.

If it's a mistake -- in this case -- I would say it's a -- it's a grammatical mistake.

Q. That's fine. This is all your work?

A. This is my work, sir.

(A discussion is held off the record.)

Q. Second full paragraph, the last sentence, you are talking about "the final distribution of a batch within which a pharmacist who was dispensing the product in the field reported "double-thick" tablets."

Do you see that sentence?

A. Yes, sir.

Q. The next paragraph starts with the reference to Batch 70924. Do you see that?

A. Yes, sir.

Q. Are you talking about two different batches?
A. No, sir. I'm not.
Q. So do you believe that a pharmacist somewhere in the United States found a double-thick tablet that was made as part of Batch 70924 in November of 2007?
A. That's -- That's my understanding, yes, sir.
Q. I would like you to dig through whatever documents you need to dig through to find that for me, because that would be a revelation.
MR. MORIARTY: And, Pete, if you know what he is referring to, by all means help him to speed this up.
MR. MILLER: All right, I will.
(A discussion is held off the record.)
A. I realize I'm wasting your time. It's going to take me a bit. I thought I had it here.
Q. Do you remember what the content of that exhibit is?
A. It was a -- as I recall, it was --
Q. No, wait. Yes or no. Do you remember it enough to answer questions about it?
Because I know what you are talking about.
A. Okay.
MR. MILLER: I would object to him answering off of memory.

A. Yeah, I think --

MR. MORIARTY: Maybe he has enough memory to answer it. That's what I asked him.

A. Right.

MR. MILLER: That's what I objected to.

Q. He objects to your memory.

MR. MILLER: No. I object to your question.

Q. Do you have enough memory of that exhibit to answer questions about it?

A. Why don't you ask me the question.

Q. Sure.

A. And then you know what? If I can't accurately answer it, I'll answer yes or no.

Q. Do you know whether that was found by a pharmacist or somebody at a nursing home?

A. As I recall it was a pharmacist. Whether he was at a nursing home, I don't recall.

Q. Do you know if it was in a blister pack or in a bottle?

A. That I don't recall.

Q. Do you know if it was weighed?

A. That I don't recall either.

Q. Do you know if it was measured?

A. No.

Q. Do you know if it was ever returned to Mylan

or Actavis?

A. I believe it was part of a complaint.

Q. Was it ever returned to Mylan or Actavis?

A. Not to my knowledge.

Q. Was the e-mail that you looked at an internal Mylan e-mail?

A. I don't remember the format.

Q. Was there actually correspondence from the person who supposedly saw this directly to Mylan or Actavis?

A. The person who found it?

Q. Yeah.

A. No, sir. That's -- that I do remember.

Q. Okay. Would you agree with me -- you know what a blister pack is; right?

A. Absolutely, sir.

Q. Would you agree with me -- I'm sorry. Let me ask another question first.

Let's assume it was in a blister pack. Do you know whether the blister pack was ever opened so that they could actually inspect the tablet?

A. I couldn't answer that, because I don't remember it being in a blister pack either.

Q. But if -- if it was in a blister pack and they didn't remove it to weigh or measure it, would

you agree with me it would be extremely difficult to see through the pack as to what the actual size was?

MR. MILLER: Objection.

A. If you are asking me -- if I was asked to measure the tablet that was inside of a blister pack, my answer to that would be that's impossible to do accurately.

Q. Okay. If you were asked to do an investigation of an incident where somebody reported that there was a double-thick tablet, wouldn't you try to have some communication with the person who supposedly saw it?

Let me go back and ask a different question.

A. Okay.

Q. Okay. I'll withdraw that question.

Let's assume that one of your consulting clients calls you and says, We think we may have released some extra-thick tablets. We have a report, a third-hand report, of somebody in Massachusetts at a nursing home who may have one. We want you to look into it." Okay? Now, let's go from that premise.

Would you try to communicate with the nursing home person in Massachusetts who supposedly saw it?

MR. MILLER: Object to form.

Q. Yes or no?

A. I would ask to see the sample first.
Q. Okay. You'd ask to see the sample?
A. Yes, sir.
Q. And if it was in a blister pack, would you open the blister pack?
A. Yes, sir.
Q. Would you weigh it? The tablet.
A. Yes, sir.
Q. Would you measure it?
A. Yes, sir.
Q. Would you consider submitting it to a lab for testing for its active pharmaceutical ingredient content?
A. Customarily I would, because that was how I did things, yes, sir.
We didn't -- I wouldn't call the guy at the nursing home. We didn't get that far.
Q. Well, if you couldn't return the sample, would you call the person at the nursing home to find out what they actually did to analyze it?
A. I think, if I understand -- maybe I'm having trouble with understanding the question. I'm not trying to be stupid.
They found it. They reported it, but they didn't send it back. Did I get that? Is that the

question?

Q. Yeah. But if it wasn't weighed, wasn't measured, wasn't taken out of the blister pack, we don't even know who this person was, what their qualifications were, whether they're a pharmacist, a nurse or ward secretary, that isn't a very reliable report for you to go on as a pharmaceutical investigator; is it?

MR. MILLER: Object to form.

A. You would have to determine that person's credentials in the building, yes.

Q. Would you agree with my statement that's not a very reliable report if none of that was done?

MR. MILLER: Objection.

A. I would say yes, that you would have to have more reliability.

Q. Dr. Somma, since we are going to be going all day, we do take periodic breaks. I'm willing to keep going. But if you need a break now, I'm about to change subjects. Okay?

A. Okay. Can I stand up, then?

Q. Sure, you can stand up.

MR. MILLER: All right. We'll take a break.

Is that what we're doing?

A. Is that okay?

Q. I don't need a break. Do you want to just stretch your legs and sit right back down, or do you want a general break?

A. I was going to hit --

Q. Then let's take a break.

THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 9:37 a.m. This is the end of Tape 1.

(A discussion is held off the record.)

MR. MORIARTY: This is the first witness that I've deposed who's said that he has seen that document. If you sent that to your other experts, I need to know. Because no one else has mentioned that document.

I don't need to know today.

MR. MILLER: Right. Okay.

MR. MORIARTY: I don't want you to guess.

MR. MILLER: Yes. I need to confirm and get back to you.

MR. MORIARTY: I just need to know before we take any more depositions.

MR. MILLER: Fair enough. I will get back to you.

(A recess is taken.)

CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

THE VIDEOGRAPHER: We are back on the record. The time is 9:45 a.m. This is the beginning of Tape Number 2.

Q. Dr. Somma, I'd like you to go to Page 7 of your report, Exhibit 52, please.

A. Okay.

Q. The first full paragraph is referring to dedusters and metal detectors. Is that right?

(A discussion is held off the record.)

A. I'm sorry, Matt. May I have the question again?

Q. All I asked is: Are you talking about dedusters and metal detectors --

A. Yes.

Q. -- in that paragraph?

Is it routine in the pharmaceutical tableting process to have dedusters and metal detectors?

A. Yes, sir, very common.

Q. Why?

A. The deduster -- the first -- the deduster is to take off, you know, loose powdered material, makes it easier to go through, make a cleaner product in the packaging, less contamination of bottles, cleaner operation.

Metal detectors are to pick up any metallic material which may come off as a piece of a machine, broken part, small things. And a metal detector is to assure that that does not happen.

Q. Did they use metal detectors at Novartis in the tableting process?

A. Yes.

Q. Okay. Now I'd like you to go to the next paragraph. You're talking about sample frequency.

Do you see that?

A. Yes, sir.

Q. I want to ask you about that.

Would you agree with me that you cannot chemically test every tablet in a production line, because you would have nothing to sell to the consumers?

A. That's correct, sir.

Q. So it is routine in the pharmacy industry to do a couple of things. One is in-process sampling of weight, thickness and hardness and appearance. Is that right?

A. That's right.

Q. And then when you have finished tablets, a certain sample of them are sent to the Quality Control lab for assay and content uniformity testing?

A. That's correct.
Q. Is that right?
A. That's correct.
Q. Now -- And typically does the ANDA contain information about how many times per half hour, hour, whatever the sequence is going to be, for the in-process testing?
A. Yes, the ANDA does, yes.
Q. And the ANDA would contain information about the size of the samples of finished tablets that would be sent to QC for assay and content uniformity?
A. Yes, sir.
(A discussion is held off the record.)
Q. So the FDA approved the ANDA for this product; did they not?
A. Yes, sir.
Q. As a matter of fact, I hand you Exhibit 6, tell me if you have seen that before?
A. Yes.
Q. First, have you seen it before?
A. Yes, I recall seeing it.
Q. It's the FDA's letter to Amide, the predecessor to Actavis, approving the ANDA; correct?
A. Yes, sir.
Q. And presumably FDA was fully aware from the

contents of the ANDA as to what the sampling plans were?

MR. MILLER: Object to form.

A. The sampling plans were in the ANDA, correct.

Q. All right. Are you familiar with current Federal Regulations 211.110C about sampling?

A. No, sir.

Q. All right. Do you know of any regulation in the CFR that's part of the pharmaceutical manufacturing guidelines which specifies either the frequency of in-process testing or the number of tablets that are analyzed during production runs?

A. As I recall, I am not an expert in that area, but as -- as I recall, you look to things like the USP for guidance on sampling and testing.

Q. Okay. Were the Amide and Actavis in-process sampling plans in the batch records?

A. As I recall they were, sir.

Q. Did the FDA have every opportunity to look at those and comment upon them if they wished between 2004 and 2008 when they did their inspections?

A. Yes, sir.

Q. And have you seen any warning, observation or other comment by FDA in the 483s or the warning letters to the effect that Actavis' in-process

sampling plans were inadequate?

A. Can I just refer to one of these?

MR. MILLER: Certainly.

A. What I wanted to check back, to answer your question now, is you asked specifically to FDA input, and I double checked; and to my knowledge -- to my recollection, they had no problem with the sampling frequency.

Q. Okay. And I skipped. I didn't ask you about this. But, you know, certainly the blend uniformity sampling plan: The number of samples, the type of sampling they used, the locations in the blender, that's all in the ANDA; is it not?

A. That information was in the ANDA. What I -- and it looks like these things have continued to be worked on and progressed at Actavis.

Q. Okay. And they are in the batch records; are they not?

A. They sure are, as planned deviations, which means it is over and above what they had indicated they wanted to do.

Q. Okay. All right. And I don't want to talk about blend uniformity investigations right now. But as far as the sampling plans are concerned, did you ever see any FDA observation warning letter or 483

criticism of the actual blend uniformity sampling plan itself?

A. Looking, again, at what I just looked at, I just -- my -- my answer would be no.

Q. And then the finished product testing; the number of finished products they sent for assay or content uniformity, that was in the ANDA and in all the batch records. Is that correct?

A. That's correct.

Q. And have you seen any FDA warning, observation, criticism, regarding the finished product testing sampling plan?

A. I have not, simply because Actavis very diligently followed USP requirements, which are a minimum standard here.

Q. Now let's go back to your report.

A. Uh-huh.

Excuse me, Matt. Do I need to hand you back these things?

MR. MILLER: No.

Q. No. Actually, put them on that bigger stack there.

A. Oh, okay.

Q. I'd like you to look at -- What I did is I took your references in your Appendix A of your report

and I created a binder. And I did them by the numbers in order of your appendix. Okay?

A. Okay.

Q. So I'd like you to look at your Reference Number 4.

A. Which would be Methods For Drug Substance and Drug Products From the ANDA?

Q. Yes. Was this validated?

A. All of their methods were validated.

Q. All right.

A. Yeah.

Q. I don't see anything -- Do you see anything in the FDA regulations that indicates that there is a mandatory time period in which you need to re validate a particular process?

A. That really depends on the firm's approach to things. And, again, I'm not trying to be vague. FDA gives a firm the ability to operate their business in their own best interests. And that has to be done by an internal review.

So basically I'm answering the question: FDA doesn't say you have to do this every year or every six months.

Q. Okay.

A. That's been my experience.

Q. I didn't see anything in your report to indicate that the test methods contained in Reference 4 of your report were no longer valid in 2006, 2007 or 2008.

A. No.

Q. Is there anything in your report about that?

A. No, sir.

Q. So I assume you have no opinion to a probability to the effect that these were somehow not valid in 2006, '07 or '08. Is that right?

A. My opinion in that case is that they were valid, yes, sir.

Q. All right. So let's go back to your report.

A. Yes, sir.

Q. Page 5. You have a comment here.

A. Yes, sir.

Q. -- in the last paragraph before Packaging, it says, "We did not consider the sample frequency (every hour) used during the compression phase of the manufacturer to be adequate."

Do you see that?

A. Yes, sir, and that is the error that I wanted to bring up.

Q. All right. Well, I'll get there.

A. Okay. You know, Matt, because I know I'm not

supposed to ask you questions, but what page are you on again?

Q. Seven.

A. Oh, I'm looking at Five.

MR. MILLER: You said Five.

Q. Sorry. Well, wait a minute. Wait a minute. I'll -- I'll fix this.

Let's go back to Five.

A. Okay.

Q. At the end of the first paragraph on that page, you refer to "These tests are conducted on an hourly basis."

Do you see that? On Page 5. Last sentence, first paragraph.

A. Yes, sir; yes, sir.

Q. And then at Page 7, you were critical of the sample frequency because it was only every hour; correct?

A. Correct.

Q. All right. Have you looked back at the records?

A. Yes, sir.

Q. And you recognized that its QA comes in every hour. Is that right?

A. That's correct, sir.

Q. And the tablet press operator checks every 30 minutes?

A. Yes, sir.

Q. Correct?

A. Correct.

Q. So within the space of an hour, there are actually three checks. Is that right?

A. With counting the QA, yes, sir.

Q. Yes. All right. So if we were to dig back into Mr. Bitler's report, that is Plaintiff's Exhibit 16, we would find --

MR. MILLER: I don't believe you have handed him that.

THE WITNESS: Oh, okay.

MR. MORIARTY: I haven't. He has it in his material.

Q. Would you like your own copy of it, or can we refer to --

A. Just to be clear, that's the deposition?

Q. No. Your Reference 15 -- I'll just hand this to you.

A. Thanks, Matt.

Q. I've even flagged the pages.

Your Reference 15 is Dan Bitler's report, which is Plaintiff's Exhibit 16; correct?

A. Yes, sir. Okay.
Q. And if you go to Page 12, and the page numbers are handwritten, and I flagged one of them for you.
A. Oh, I got you. Yes, sir. Go ahead.
Q. The operator checks for Press 67 are at 7:45, 8:15 and 8:45; correct?
A. Yeah, I'm still looking for the press number.
Q. It's on the preceding page, actually. You see this is Page 2 of 5?
A. Got it.
Q. The press number is on Page 1 of 5.
A. Okay. I got it. Okay.
Q. Yes.
A. And yes, 7:45 and 8:15, yes.
Q. Okay. And then if you go to Page 20, which I've also flagged for you, these are the QA checks, same press, 7:20 and 8:20; right?
A. One hour, at one hour.
Q. So what is the correction that you want to make to your report?
A. Well, the correction is what I had -- my comment was that every half hour I thought was the operator -- every hour was the operator testing. So it should be every half hour.

Q. All right. So with a sampling frequency of three times in an hour, you'd agree with me that that is adequate in-process sampling; correct?

A. Three times in an hour is a good level of sampling, yes.

Q. Do you know what the application integrity policy is?

A. No, sir.

Q. Are you generally familiar with any regulations promulgated by FDA regarding what they expect in the way of accuracy and honesty in pharmaceutical records, pharmaceutical manufacturing records?

A. No, sir. I was -- I always assumed that it was accurate based on our requirements internally. I didn't realize it was a regulation, no, sir.

Q. Well, what do you think FDA would have done to Novartis, for example, if it found falsified data in a batch record?

A. Falsified?

Q. Falsified.

A. Well, my only experience there was, you know, a contractor we had used. The answer to your question: It's severe.

Q. It's severe. Okay. In other words, you --

you assume that these records are supposed to be accurate and reliable and honestly done; correct?

A. Yes, sir.

Q. In all of your review of this material, did you see any FDA Form 483, any FDA warning letter or any comment in the establishment inspection reports that found that the company had falsified any documents or data?

A. No, sir, I did not see anything as far as falsification.

Q. All right. So I assume that as you reviewed the material, you did not have any reason to question the accuracy of, for example, a batch record --

A. No, sir.

Q. -- or an annual report?

THE WITNESS: Sorry, Mark.

A. No, sir. When I read this, my understanding was that this was accurate and true.

Q. All right. Now, in that stack in front of you --

A. Yes, sir?

Q. -- those exhibits were marked the other day, and they are actually in their numeric order. So if you go towards the bottom of the stack. I want you to look for Exhibits 63 and 64. Okay?

(A discussion is held off the record.)
A. Sixty-three, is this correct?
Q. Yes. And 64 would be right behind it?
A. All right. Chapter 10.
Q. I want you to look at 64 first.
A. That's Chapter -- I'm sorry? Correct.
Q. Yes. Have you ever seen this before?
A. Regulatory Procedures Manual, no. I'm aware of its existence. Have I looked at this? No, sir.
Q. Do you know that this is a document of FDA's?
A. Yes, sir.
Q. I would like you to turn in Exhibit 64 to Page 10-7.
A. Okay.
Q. Section 10-2-4, Procedures. All right?
A. Yes.
Q. The first sentence there says, "Warning Letters are the principal means by which the agency provides prior notice of violations and of achieving voluntary compliance."
Do you see that?
A. Yes, sir.
Q. Do you agree with it?
A. Yes, sir.
Q. Later in that -- in that opening, it says,

"Prior Notice may be provided by means of a civil suit, administrative action or other less-formal ways, including the following."

Number 2 is the issuance of a 483. Is that right?

A. That's what -- yes.

Q. And Number 3 is "Discussion with management by an FDA investigator, documented in the EIR"?

A. Yes, sir.

Q. Is that right?

A. Right.

Q. So if I'm reading this correctly, and you tell me if you agree, according to FDA's own manual, they consider a 483 and an EIR less formal than a warning letter. Is that right?

A. My personal -- my personal opinion, yes. I would agree with that.

Q. All right. So let's now turn to Exhibit 63.

A. Okay. Chapter 4.

Q. I want to go to the second page, Page 4-2.

A. Okay.

Q. Fourth full paragraph.

A. "FDA is under no," is that it?

Q. Fourth full paragraph. So it's the next one.

A. Okay.

Q. "A warning Letter is informal and advisory."

Do you agree with that?

A. Well, I never -- we never dealt with them as an informal thing. To me it's pretty serious stuff. But if that's their opinion, fine.

Q. Okay. "It communicates the agency's position on a matter, but it does not commit the FDA to take enforcement action."

Do you agree with that?

A. That has been my experience, yes, sir.

Q. All right. And the last sentence says, "For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued."

Do you have any reason to disagree with FDA's comment on that?

A. There is no reason for me to disagree, no, sir.

Q. Do you have an expertise on what a "final agency action" means?

A. Only in a limited sense on a particular client that we have now; okay?

Q. You can put those back in the stack. I'm done asking you about those.

A. Okay. Okay.

Q. I'd like you to go to your Reference 18,

which is a 483 from the inspection of March 18 through May 20, 2008.

MR. MILLER: That's the EIR. I think he's asking about the 483.

(A discussion is held off the record.)

A. 3/18/2008 to 5/20/2008; correct, Matt?

Q. Yes, sir.

A. Okay.

Q. Go to Observation 2.

Do you know what the FDA's Turbo software is?

A. No, sir, I don't.

Q. If you look at Observation 2, the first thing that it says is "Drug products failing to meet established specifications and quality control criteria are not rejected."

Do you see that statement?

A. Yeah, I do, yes, sir.

Q. Is that a restatement of a regulation?

MR. MILLER: Object to form.

A. I don't think that's a restatement. It sounds like it's an opinion. But, again, I'm not -- I'm not an expert in the verbiage of the regs. I'm not -- it seems like it's an opinion.

Q. Did you ever read the deposition of a Quality Assurance person in this case by the name of Chuck

Koon?

A. No, sir.

Q. Well, what Mr. Koon said is that the statement I just read to you is essentially spit out of something called the FDA's Turbo software as a regurgitation of a regulation, and that what follows under the phrase specifically is the actual factual observation made by FDA at the time of their inspection.

Do you have any reason to disagree with him on that?

MR. MILLER: Object to form.

A. No, sir.

Q. Have you ever looked at the FDA's definition of the term "adulteration"?

A. Yes, sir.

Q. Is it something that you reviewed in your preparations for opinions in this case?

A. I looked at it because -- you know, like I said, I'm not an expert in regulatory stuff, so I made sure at least I had an understanding of it, yes, sir.

Q. All right. I would like you to look in that stack and see if Exhibit 39 is in it.

(A discussion is held off the record.)

Q. Is it there?

A. Yes, sir.
MR. MORIARTY: Pete, do you still have your own or do you need an extra?
MR. MILLER: I've got my own.
Q. Okay. Dr. Somma, have you seen this Exhibit 39 before?
A. I don't -- I don't recall seeing it like this, sir. Was this part of something else?
Q. I'm just asking if you have seen it.
A. Not -- no, sir.
Q. All right. This is a printout from the FDA's web -- website in a section called "Facts About Current Good Manufacturing Practices."
Do you see that at the top?
A. Yes, sir.
Q. All right. I first want you to go under "What are cGMPs" and go to the second full paragraph.
A. Okay.
Q. It says there "The cGMP requirements were established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods and testing procedures."
Do you see that?

A. Yes, sir.
Q. Do you agree with that?
A. Yes, sir.
MR. MILLER: Objection to form.
I'm sorry.
MR. MORIARTY: I'm not sure how that can be objectionable to form, when I say "did you agree with it."
And by the way, Mark, the court reporter, when I say cPMG the C is small, the G-M-P are all capitalized.
THE REPORTER: Thank you.
Q. Let's go to the second section, which says, "Why are cPMG's so important?" The second -- I'm sorry. The third sentence says, "In most instances, testing is done on a small sample of a batch (for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets), so that most of the batch can be used by patients rather than be destroyed by testing."
Do you agree with that?
A. Absolutely.
Q. Now, let's go down to the fourth section, entitled "If a manufacturer is not following CGMPs, are drug products safe for use?" And the first two

sentences there talk about what adulteration means. Is that right?

A. Yes, it does.

Q. And then the third sentence says, "It does not mean that there is necessarily something wrong with the drug."

Did I read it correctly?

A. Yes, you did.

Q. Do you agree with it?

A. I think -- in this particular case, I think everything has to be taken in balance, unfortunately. I think you have to look at the whole subject. This is true on balance if everything else is correct. That's all I'm saying.

Q. So in general, and I'm not referring specifically to Digitek right now. I'm saying, in general, you agree with the FDA's statement about that?

A. If everything else is in place, yes, sir.

Q. All right. Go to the next paragraph. About two-thirds of the way down it says, "The impact of cGMP violations depends on the nature of those violations and on the specific drug involved. A drug manufactured in violation of cGMP may still meet its labeled specifications and the risk that the drug is

unsafe or ineffective could be minimal."

Do you agree with that?

A. It has been my experience, sir. That doesn't negate the firm -- or the firm in this case being subject to regulatory scrutiny. That's also my experience, yeah. Okay?

Q. So if I understand what the FDA is saying on their own website, essentially "adulteration" does not mean necessarily that the end product that gets to the consumer is defective. Is that true?

MR. MILLER: Objection to form.

A. That adulteration is a correct statement when all of the other moving parts making a product are correct, yes.

Q. I need you to answer my question.

A. I got you. Okay.

Q. If I understand what FDA is saying in this website, "adulteration" does not necessarily mean that the end product in the hands of the consumer is defective or out of its specification. Is that correct?

A. That would be my experience, yes, sir. Sorry.

MR. MILLER: You're fine.

Q. Okay.

A. Are you done?
Q. If you could just put it back on the stack or in the stack. We'll clean up in a few minutes.
I'm handing you what's been marked as Exhibit 1. Have you ever seen this process validation report before?
A. I have seen a process validation report, but not for this strength.
(A discussion is held off the record.)
Q. All right. Exhibit 1 is the process validation for the 125 microgram product; correct?
A. Correct.
Q. Do you know which process validation report you saw?
A. 0.5 milligram, or 500 microgram.
Q. Do you have any memory of when that ceased to become a commercially produced dose by any manufacturer?
A. No, sir.
Q. Okay. Here's Exhibit 2.
A. Okay.
Q. This is a process validation report for the 250 microgram product. Have you ever seen this before?
A. No, sir.

Q. Do you have any -- and these would have been the kind of things done in advance of submitting the ANDA to the FDA for approval of the product; correct?

A. No, sir. Customarily validation is done once submission is made. Depends on company policy. There is no requirements.

Q. Okay.

A. My experience.

Q. But these are the validate -- what is validation?

A. Validation is to confirm that everything that has been put in place: Specifications, systems, quality approach, is going to work once you -- once you make the product, and reliably so. Customarily validation is done three times. The current practice is it's through the entire product life cycle. Okay?

Q. All right. Would you agree that "Validation is establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes"?

A. I will agree with that, and further --

MR. MILLER: Go ahead.

A. And further, that today it's assumed that it meets these requirements through its entire product

life cycle.

MR. MILLER: And Matt, to keep the record complete: You were reading from a document. Can I ask what document you were reading from?

MR. MORIARTY: It's my own research document.

A. Right. I've heard that statement before.

MR. MORIARTY: If it was a published source I would be happy to tell you, but I don't know where it's from.

MR. MILLER: Got it.

A. Vaguely familiar, though, Matt. Very good.

Q. Can you see if Exhibit 46 is in that stack?

A. I sure can.

(A discussion is held off the record.)

A. Okay.

Q. This is an article coauthored by one of the other plaintiffs' witnesses in this case, Mr. Farley.

Have you ever seen this article before?

A. No, sir.

Q. And just so you know, one of the co- -- the coauthor, Mr. Brooks, is a lawyer; okay?

Go to the last sentence of the first page, please.

A. Okay.

Q. It says, "The FDA's acceptance of submitted

procedures is evidence, not conclusive proof, of the reasonableness of the company's manufacturing practices and procedures."

A. I'm sorry, Matt.

Q. Do you see that?

A. I'm sorry, Matt.

Q. I'd like you to go to the very bottom. Let me have it back. It's possible it didn't copy this.

Yeah, right there, the last sentence on that page.

A. Okay. The FDA's regulation?

Q. No. I'm going to start over. The last sentence on the page.

"The FDA's acceptance of submitted procedures is evidence, not inclusive proof, of the reasonableness of the company's manufacturing practices and procedures."

Have I read that clause accurately?

A. Yes, sir.

Q. Do you agree with it?

A. I think, yes, sir; because it aligns with what I said before. In the end, the owner of the product is the custodian of the product. That's what this says.

Q. Go to Page 3, please. While I've got this, I

may as well ask you everything I need to about it.

A. Yes, sir.

Q. There is a caption called "Pre Filing Investigation." Do you see that?

A. Yeah.

Q. And it says, "When a client comes to you suspecting that he or she has taken an adulterated drug, you should tell the client to save the drug, the container, and all labeling and packaging information."

Do you see that?

A. Yes, sir.

Q. The next sentence says, "A laboratory must analyze the drug to test for its active pharmaceutical ingredient and for strength and purity."

Do you see that?

A. Yes.

MR. MILLER: Object to form.

Q. Do you agree with it?

A. Well, actually, I agree with him. It's what I had said it before, Matt.

Q. Okay. Go to Page 4. At the very bottom it should say, "Training records" in bold.

A. Okay.

Q. Have you looked at any training records in

this case?

A. No, sir.

Q. Go to Page 5, please. The second bolded section is called "Standard Operating Procedures."

A. Yes, sir.

Q. Have you looked at any SOPs of Actavis or Amide?

A. Yes, sir.

Q. How many of them?

A. I looked at -- my guess would be three or four around the specifics that I was looking at, compression.

Q. Do you know, either by number or topic, what those SOPs were?

A. One was compression, using the Stokes machine, and the other was the blending of powders. I don't remember the numbers.

Q. Okay.

A. I'm sorry.

Q. All right. I don't have any questions about that. You can put that back on the stack.

A. Is this -- what is this? I'm sorry.

Q. All right. I want to ask you some questions about manufacturing processes for solid oral dose --

A. Yes.

Q. -- pharmaceutical products; okay?

In the ANDA and in the batch records, is the formula for the product there?

A. Yes, sir.

Q. And the formula has the ingredient and the amount of the ingredient that is supposed to go in; correct?

A. Yes, sir. It has the dosage form amount as well as the amount that goes into the batch to make the product, yes, sir.

Q. And presumably those ingredients need to be mixed in the appropriate proportions in order to comply with the formula. Is that right?

A. That's correct.

Q. And typically when the actual mixing is done, one person mixes it and a second person verifies by watching that that is done appropriately. Is that right?

A. Customarily, yes, in all cGMP environments, one guy does, one guy verifies.

Q. All right. And if we were going to do an investigation of tablets that were normal in size, but somehow out of their finished product specifications and just, for example, let's say on the high side, one place you might look is whether the batch was mixed

appropriately from the start; correct?

A. Yes, sir, that's the standard review, batch record review.

Q. You would want to know whether they put too much active pharmaceutical ingredient into that batch or other batches; right?

A. Right. We check by the weight sheets.

Q. Have you seen any FDA citations or warnings in any FDA 483 or warning letter to the effect that Actavis improperly mixed Digitek?

A. No, sir. Everything that I've reviewed suggests that the process was done according to the way it's written.

Q. Once the ingredients are mixed, do they weigh it?

A. There are steps that they confirm that the material has been put in and removed. That's customary when you do a process transfer from a blender to a drum to a blender. Yes, sir, they do do that.

Q. Okay. Why do they do that?

A. That's to confirm that they haven't had any untoward losses during the manufacturing, okay? A drop on their shoes.

Q. I guess theoretically you don't want any

untoward gains either. Is that right?
A. Right. Gains is much worse than loss, correct.
Q. And this sort of weighing --
A. Yes.
Q. -- at each stage of the process is sort of a quality check to see whether you have untoward gain or loss; right?
A. Absolutely.
Q. And also, if you have validated the process, it gives you a benchmark so you know whether you're meeting targets from your validated processes; correct?
A. Correct.
Q. Do you know what yield calculations are?
A. Yes, sir.
Q. Are you familiar with doing that yourself --
A. Yes.
Q. -- at Novartis?
A. Yes, sir.
Q. In any of the batch records you reviewed, did you see any inappropriate yield calculations?
A. Absolutely not, sir; they were done correctly.
Q. Did you see -- I'm sorry.

Did you see any FDA warnings or 483 citations to the effect that the yield calculations were somehow trending inappropriately?

A. That I did not see, sir.

Q. Let's talk about blenders.

A. Okay.

Q. Tell me about your actual experience in operating blenders or conducting blend uniformity sampling.

A. I established the SUPAC equipment guidance of similarity for FDA, the formal industry guides; so my -- my understanding of the blending aspect was key in that case. Our objective was to determine like versus like.

As far as blend uniformity, it's expected in all products prior to launch. And I've done 21 NDAs.

Q. Okay.

A. Okay. You asked for background. Sorry.

Q. At Page 10 of your report --

A. Yeah.

Q. -- you are talking about how at Actavis the final step blender is of a different geometry?

A. Correct.

Q. Do you see that?

A. Yes, sir.

Q. Okay. Was this change of geometry -- I'm sorry.

MR. MORIARTY: Let me withdraw that question.

Q. Was the blender configuration in the ANDA --

A. Absolutely, sir.

Q. -- approved by the FDA?

A. Yes, sir, it was in there.

Q. It's in all the batch records?

A. Yes, sir.

Q. Has FDA ever made a citation or warning or criticism of Actavis or Amide for its blender configuration with Digitek?

A. No, sir. This is simply my opinion.

Q. Now, you referred at various points in your report to a book called "Pharmaceutical Process Scale-Up."

A. Uh-huh.

Q. Did you not?

A. Yeah.

Q. You brought it with you?

A. I didn't know if you would have a copy.

Q. I just happen to.

What edition do you have?

A. It was only the one, Matt, but let me check.

Q. That's okay. That's fine. I don't see an

edition on mine either.

A. It wasn't exactly a best seller.

I've got a copyright of 2002. Okay?

Q. Okay. So at least two of us have looked at this book?

A. Yes, sir.

Q. And the focus of this book, if you go to the preface, the first sentence of the book says, "Pharmaceutical process scale-up deals with a subject both fascinating and vitally important for the pharmaceutical industry, the process of transferring the results of R&D obtained on the laboratory scale to the pilot plant and finally to production scale."

Did I read that right?

A. You did.

Q. And essentially that's what this whole book is about; right?

A. That's what it's supposed to be about, yeah.

Q. And if you go to the next page, in the Introduction to the book, it says, "Scale-up is generally defined as the process of increasing the batch size." Do you see that?

A. Uh-huh, yeah.

Q. Do you agree?

A. Yeah. Because that's when you talk about

scale-up, right.

Q. Okay.

A. Since this book has been published, just as a point, you refer to scale-up. People prefer to just scale-out. In other words, they don't change the scale any more, Matt. They try to just make more of it.

(A discussion is held off the record.)

A. They don't scale up. They scale out.

I'm sorry, Matt, that's that that PhD. ...

Q. What does "scale out" mean?

A. "Scale out" means if you were making it -- say you were making 50 kilograms in a process. Independent of what the process is. Rather than take that and try to make 500 kilograms, you make multiple 50 kilogram processes.

So rather than take the risk of the scale, you remain small and you leverage your knowledge without taking the risk of scale-up.

Q. Okay.

A. I'm sorry.

Q. Go to Appendix C of the book, Page 415.

And while you are looking for that, this is "Pharmaceutical Process Scale-up" edited by Levin, L-e-v-i-n. Is that right?

A. Uh-huh.
Q. Go to 415, Appendix C.
A. Yeah.
Q. Is this called "Guidance For Industry, SUPAC," dash, "IR/MR, Immediate Release and Modified Release, Solid Oral Dosage Forms, Manufacturing Equipment Addendum"?
A. That's right.
Q. I would like you to go to Page 422.
A. Uh-huh.
Q. Do you know what kind of blenders Actavis used --
A. Yes, sir.
Q. -- for blending Digitek?
A. Yes, sir. A V blender and a double cone blender.
Q. Well, they were made by Paterson Kelly; correct?
A. That's correct.
Q. And if you look at Page 422 --
A. Right.
Q. -- Table 3 under diffusion blenders --
A. Right.
Q. -- both V and double cone, Paterson Kelly, are listed there; right?

A. That's right. That's how we did that.
Q. And while I got this book out, go to Page 435.
A. Uh-huh.
Q. Which is Table 6?
A. Okay. We got it.
Q. This is tablet presses; right?
A. Right.
Q. Gravity feed tablet presses, Stokes is on the list; right?
A. Yes, sir; yes, sir. It's right here. I wasn't -- I'm sorry.
Q. So at Page 10 of your report, you specifically refer to Pages 115 to 132, which is Chapter 5, called "Batch Size Increase in Dry Blending and Mixing." Do you see that?
A. That's right.
Q. And this is about scale-up, so you are going from one batch size to a bigger batch size.
Is that right?
A. That's right.
Q. And this whole chapter's about blender configuration in that situation; right?
A. Correct.
Q. Now, when Digitek was being manufactured in

2004, '5, '6, '7 or '8, they didn't change the size of the batches; did they?

A. They did scale it up from their bio pilot logs, yes, sir.

Q. Well, not in 2004, '5, '6, '7 or '8; correct?

A. Oh, I'm sorry. Yes, sir. No, sir.

Q. And the process for the manufacture of Digitek in those years was a validated process; was it not?

A. Based on the three batches, yes, sir.

Q. Okay. So is there anything in this chapter of the book to which you refer that says that the Paterson Kelly blending configuration used for Digitek was somehow against an industry standard or inappropriate?

A. When we put the SUPAC guidance on --

Q. Wait. Yes or no.

A. Sorry.

Q. Start with yes or no?

A. May I have the question again, please? Sorry.

Q. Is there anything in this chapter of the book to which you refer that says that something like the Paterson Kelly blender configuration used for Digitek was inappropriate or against an industry standard?

A. Yes.
Q. Show me where in this chapter it says that?
A. Page 119, bottom.
Q. Exactly where?
A. "Common violations," the last paragraph, Matt. Right here.
Q. I'll get there. Okay.
"Common violations of this approach can immediately cause problems, include (sic) the attempt to scale from one geometry to another." Did I read that right?
A. That's correct.
Q. And if I understand scaling in the context of this book, you are talking about going from one batch size to another; right?
A. That's correct.
Q. Which didn't happen in 2004 through '8; correct?
A. I think -- that's correct. I think my comment is in retrospect.
Q. And the FDA, I believe I may have asked you this before, never had any problems with the blender configuration?
A. No, sir, they did not.
Q. In this paragraph in your report at Page 10,

when you are talking about these blenders, you don't use the word "negligent;" do you?

A. Absolutely not.

Q. You don't use the words "against industry standards:" Do you?

MR. MILLER: Object to form.

A. Can I read it? I don't recall using those words, but let me double-check.

I do not see that word here.

Q. Let's go to the next paragraph of Page 10.

A. The evaluation?

Q. "The evaluation of blend uniformity is a difficult task."

What does that mean?

A. "Difficult task" means that it requires a -- again, what I had indicated, a very rigidly established plan that has to be followed: How the product is going to be withdrawn, how big the product is going to be, how the samples have to be handled and recovered.

Q. I want to know what you mean by "difficult task"?

A. Because there are so many different things that can contribute to a false positive or a negative -- or a positive false input.

Q. Do many companies struggle with blend uniformity?

A. I can't speak for all the companies I've worked for; however, I can tell you that many of the products I worked on, it was a struggle, yes, sir.

Q. All right. And actually -- companies actually don't have that much problem with blend uniformity? Companies have problems with blend uniformity sampling; right?

MR. MILLER: Object to form.

A. Good point, Matt. The point is -- the key is: If you have two wristwatches, what time is it? So is your sample defective or is your blend defective? That's where the difficulty in task comes in: Illucidating which is wrong and which is right.

Q. All right. Now, I can't remember whose principle or law this is; but when you test blend, you change the nature of the blend in the process of testing; do you not?

A. That comes back to sample handling. Okay? In the correct world, if you are trying -- your point is in a static bed, when you pull the sample, you have disrupted the bed; therefore, the bed is different.

Q. Okay.

A. Right?

Q. So am I correct that various pharmaceutical companies have tried to obtain exemption from blend uniformity sampling because it is such a variable and difficult problem?

A. That is correct.

Q. Are there industry groups in the pharmaceutical companies that have petitioned the FDA to do away with blend uniformity sampling because of its difficulty?

A. There has been a great deal of information transmitted on that point, yes. And I can point to that FDA does give some latitude on high-dose composition.

Q. Now, did FDA ever say in a 483 or warning letter that the process by which we test blend uniformity was inappropriate?

I asked you earlier about the sampling plan itself, where and how many, and you said no. Now I'm asking you about anything else about the actual test process.

A. Matt, I'm just looking here to make sure.

MR. MILLER: Take your time.

A. I've looked at these things. Let me just look at one more thing, Matt.

I dot not recall FDA having a problem with

the way they tested their samples.

Q. Okay. Did you review the SOP for blend uniformity sample? Actavis' blend uniformity sampling SOP for Digitek?

A. I've read all of the procedures. I don't recall if I actually read that SOP, to be perfectly honest.

Q. Now, you are aware that there is an FDA 483 about some blend uniformity investigations. Is that right?

A. Due to out-of-specifications observations, yes, I am.

Q. Now, how many batches were affected? How many batches were involved in that 483 citation?

MS. CARTER: Object to form.

A. I don't recall.

MR. MORIARTY: Did you just object?

MS. CARTER: I did.

A. I don't recall, Matt.

Q. Do you know what -- Well, you can look at the 483. My memory is it's three batches.

A. Okay. Let me look.

Q. I believe it's the May, 2008 483.

Am I wrong about that? I thought it was Observation 3, but --

MR. MILLER: Maybe it's 4.
Q. Do you see it there?
A. Okay. Three batches, Matt. Thank you, yes.
Q. So if we go by the number of recall batches, that's three out-of-spec --
Let me start from scratch.
Those three investigations had to do with an out-of-spec result in one out of ten samples for each batch; correct?
MR. MILLER: Object to form.
A. As I recall, yeah. That was -- it was the same location every time.
Q. Okay.
A. Right.
Q. And on retesting, they didn't confirm the out-of-spec result; correct?
A. They ran the replicate samples and did not see the failing result, correct.
Q. When you say "replicate samples," at the time you sample a dry blend like this, you take two or three samples from each site; correct?
A. Absolutely.
Q. So if it calls for ten sites, you are taking 20 or 30 samples?
A. Customarily 30, yes.

Q. So if the first sample at the right top fails, there are backup samples taken at the same time that you can test; correct?

A. That's correct.

Q. Is it your memory that in each of those three instances, a backup sample passed?

MR. MILLER: Object to form.

A. As I recall, yes. As I recall, they passed. Because I don't think they had to go much beyond two in one case, yeah.

Q. If you read the -- Well, did you read the actual Actavis investigations of those blend uniformity --

A. Of these particular batches?

Q. Yes, sir.

A. Honestly, I can't say that I read the ones specific to these batch numbers; no, sir.

Q. All right. Are you aware that in general with those three batches, they increased the sample size for the finished product testing?

A. To 30 tablets, yeah. That I am aware of.

Q. And all three of those batches actually passed finished product testing; correct?

A. Yes, as I recall.

Q. All right. Now, do you know how many of

those three batches were actually released and sent to the market?

A. No, sir, I don't recall that.

Q. And in that 483, isn't the FDA's real focus of their observation that Actavis did not, in addition to the QC investigation, conduct a manufacturing investigation?

MS. CARTER: Object to form.

A. Matt, I'm just reading it again. May I please have the question again?

Q. Yes, sir. Are you ready for the question again?

A. Yes, I'm going to pay attention this time.

MR. MORIARTY: Mark, can you read that one back, please?

A. Sorry.

(The question is read.)

A. Yes.

Q. So let's go back to Page 10 of your report, the second -- well, actually it's the last paragraph.

A. Uh-huh. The reliability.

Q. Your second sentence starts with the word "Repetitive failures at the same blender location."

A. Uh-huh.

Q. Do you have any other instances of